DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305
Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 13 1999

8538 '99 DEC 16 P1:

Peter S. Reichertz, Esquire
Arent, Fox, Kintner, Plotkin & Kahn
1050 Connecticut Avenue, NW
Washington, DC 20036-5339

Re: Docket No. 78N-036L
Comment No. CP20

Dear Mr. Reichertz:

Reference is made to the citizen petition submitted on behalf of C. B. Fleet Company, Inc., dated June 9, 1995. The submission is identified as Comment No. CP20 filed under Docket No. 78N-036L in the Dockets Management Branch. You requested that the tentative final monograph for OTC laxative drug products (published in the FEDERAL REGISTER of January 15, 1985, 50 FR 2124) be amended to allow for the use of a large volume tap water enema as the final cleansing step, in lieu of a bisacodyl suppository or enema, in bowel cleansing systems.

We have reviewed your submission and other data pertaining to this petition. However, additional data are needed for us to complete our evaluation.

Your petition did not specify how much water to administer in the tap water enema for use as part of your kit(s). Specific data are needed to determine the amount of water that can be safely added during the administration of the tap water enema for use with your kit(s). Further, your request did not provide specific warnings and directions for the administration of the tap water enema for use with your kit(s). Therefore, the following information needs to be provided so that we can complete our review of your petition.

1. Data demonstrating how much water is safe for administration in a tap water enema. Include demographic and medical information about the populations studied. Also provide data to demonstrate how much water is needed for a tap water enema with your kit(s) and the diagnostic procedures for which the volume(s) are appropriate.
2. Any new data that may be available for the kits, either from

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clinical trials, literature or safety databases.
3. Your rationale for selection and timing of the ingredients used in the kits.
4. The total number of kits that have been sold since the product was first marketed, and all adverse reports received regarding the kits.
5. All adverse reports for the enema bag, whether it was sold alone or as part of a kit.
6. Consumer and professional warnings and directions for your kits (including use of the enema bag) that will assure us that these products are adequately labeled and safe for the target population.
7. Any data or other information you have to support where and by whom the tap water enema should be administered.
8. Samples of the complete kits as they are currently marketed (including all consumer and professional labeling and other information that may be available for use with the kits).

Any comment you may wish to make on the above information should be submitted in three copies, identified with the docket number shown at the beginning of this letter, to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 1061, 5630 Fishers Lane, Rockville, MD 20852. If you need further assistance, please call Cheryl Turner at 301-827-2291.

Sincerely yours,

Charles J. Ganley, M.D.

Charles Ganley, M.D.
Director
Division of OTC Drug Evaluation
Office of Drug Evaluation V
Center for Drug Evaluation and Research

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: ~~DEC 15 1999~~ DEC 15 1999

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 78N-036L

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[ ] This material should be cross-referenced to Comment No. CP20

Charles J. Ganley, M.D.

Attachment